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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,962	02/16/2001	Gordon Moore Allan	454313-2338.1	6400

20999 7590 12/11/2003

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,962	ALLAN ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-86* is/are pending in the application.

4a) Of the above claim(s) *41 and 55-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-40,42-48,50-54,65-77 and 79-86* is/are rejected.

7)☒ Claim(s) *49 and 78* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/347,594.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 11, applicant added new claims 68-86. Claims 38-86 are pending, claims 41 and 55-64 are withdrawn from consideration due to non-elected subject matter. Claims 38-40, 42-54 and 65-86 are under consideration.

Double Patenting

Claims 68-86 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 38-40, 42-54 and 65-67. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 38-40, 42-54 and 65-67 are drawn to a vaccine, kit and a method of inoculating to elicit an immunological response and claims 68-86 are drawn to a composition (vaccine), kit and method of inoculating to elicit a protective response. The immunological response of the "vaccine" of claim 38 would be protective and the composition of claim 68 elicits a "protective immunological response". The components within each set of claims are the same and the compositions elicit the same protective immune response. Therefore, claims 68-86 are substantial duplicates of claims 38-40, 42-54 and 65-67.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-40, 42-54, 65-67 and newly submitted claims 68-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 22 and 24-30 of U.S. Patent No. 6,217,883 for reasons of record. Applicant states that a Terminal Disclaimer will be submitted upon indication of allowable subject matter. Until the Terminal Disclaimer is received, this rejection is maintained because the instant claims are not patentably distinct from the claims of '883.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is drawn to a composition for eliciting a protective immune response against porcine parvovirus and an immune response against porcine circovirus. Although the claim does not specifically state that the immune response against porcine circovirus is protective, subsequent claims imply that it is by referring to the composition as a "vaccine". It is unclear if applicant intends a difference between a protective immunological response and an immunological response against the porcine circovirus antigen. This rejection also affects claims 69-86.

Claims 69, 70 and 72 recite the limitation "vaccine" in line 1. There is insufficient antecedent basis for this limitation in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-40, 42-48, 50-54, 65-77 and 79-86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preventing porcine circovirus type II infections with inactivated PCV-II and an inactivated or attenuated porcine parvovirus, does not reasonably provide enablement for treating PCV-II infections with inactivated or attenuated PCV-1 or PCV-II and porcine parvovirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are drawn to a kit, method of inoculating and a vaccine to elicit a protective immune response against porcine parvovirus and porcine circovirus by administering an inactivated or attenuated porcine circovirus and porcine parvovirus. The claimed compositions encompass any circovirus, but more narrowly encompass PVC-II. The nature of the invention is to treat and protect against PCV-II infections since the claims are drawn to "vaccine" compositions. A "vaccine" is defined as a suspension of materials administered to prevent and treat infectious diseases, see Dorland's Illustrated Medical Dictionary, 28 edition. Philadelphia, WB Sauders, 1994, page 1787. Applicant has submitted data demonstrating that inactivated PCV-II elicits an antibody response and protects against pathogenic PCV-II challenge. However, the data does not demonstrate enablement commensurate in scope with the claims.

The claims require that the vaccine compositions comprise at least one attenuated or inactivated porcine parvovirus antigen and porcine circovirus antigen. Although there is no indication that piglets in the experiments discussed by applicant received the porcine parvovirus component, porcine parvovirus vaccines are well-established in the pig vaccine art. Therefore, this additional component would only further protect piglets from viral infection. However, there is no data in the examples discussed by applicant that would indicate amelioration of PCV-II disease upon adminstration of the inactivated PCV-II virus. There are no working examples involving pigs demonstrating symptoms of PCV-II infection and subsequent treatment of disease upon administering the instant composition. The prior art does not teach how to treat pigs suffering from PCV-II infection and the disclosure does not remedy this lack of teaching in the art. The skilled artisan would be unable to predict how to treat PCV-II infection from the information available. As discussed above, the claims are drawn to a vaccine comprising inactivated or attenuated PCV. However, there are no working examples or guidance provided by the inventors which disloses how to sufficiently attenuate PCV so that the virus remains antigenic enough to be protective and therapeutic, while being unable to cause or exacerbate disease. There is no teaching in the prior art that discussed attenuation of PCV and the skilled artisan would be unable to make an attenuated PCV that is protective and ameliorative, which is required by the vaccine claims. The skilled artisan would also be unable to use PCV to protect and treat PCV-II infection that is not sufficiently attenuated. The claims also encompass administering inactivated or attenuated PCV-1 to treat and prevent PCV infections. However, PCV-1 does not cause disease in pigs, see page 1 of the specification. There is no indication that administration of PCV-1 would treat or provide protection against PCV-II infection in the circovirus art or the

disclsoure. The vaccine claims necessarily require evidence to support the asserted protective and ameliorative effects with all of the components encompassed within the composition. Since the prior art does not teach efficacious treatment of pigs already infected, sufficient attenuation of PCV-II or cross-protection or amelioration of PCV-II infection by administering PCV-1, the skilled artisan would not predict, in the absence of proof to the contrary, that the active agents claimed are efficacious in treating PCV-II infection without an undue quantity of experimentation.

Allowable Subject Matter

Claims 49 and 78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The scope of enablement rejection could be obviated by amending the claims to encompass a vaccine to protect against PCV-II infections with inactivated PCV-II and attenuated or inactivated porcine parvovirus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley